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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,674	12/11/2003	Leisa Johnson	ONYX1033-CIP2	9520
37499	7590	02/10/2006	EXAMINER	
ONYX PHARMACEUTICALS, INC. 2100 POWELL STREET 12TH FLOOR EMERYVILLE, CA 94608			MONTANARI, DAVID A	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,674	JOHNSON ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,30-33 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,30-33 and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's arguments and amendments filed 11/16/2005 have been entered.
2. Claims 1, 30-33, and 36 are amended.
3. Claims 37-41 are newly added.
4. Claims 2-29, and 34-35 are cancelled.
5. Rejection of claims 1, 30-33, and 36 under 35 USC 112, first paragraph is withdrawn.
6. Rejection of claim 1 under 35 USC 102(b) is withdrawn.
7. Claims 1, 30-33, and 36-41 are examined in the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 remains provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/303,598 for reasons of record in the office action mailed 09/08/2005. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 1 remains provisionally rejected under the judicially created doctrine of double patenting over claim 1 of copending Application No. 09/714,409 for reasons of record in the office action mailed 09/08/2005. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 1 of the instant application encompasses the scope of claim 1 in pending applications 09/714,409 and 10/303,598.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

Applicants argue in amendment filed 11/16/2005 that amended claim 1 in the instant application obviates the provision double patenting rejection over claim 1 in co-pending applications 10/303, 598 and 09/714,409. This is not persuasive. Newly amended claim 1 in the instant application still remains within the scope of claim 1 in applications 10/303, 598 and 09/714,409. The limitation that the adenoviral vector in the instant application further comprise adenoviral packaging sequences that differ in the number of adenoviral packaging sequences, or position of said adenoviral packing sequences when compared to Onxy-411 does not further

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limit claim 1 of the instant application from that of claim 1 in applications 10/303, 598 and 09/714,409. Onxy-411, as defined by the instant specification on page 41, is taught to comprise two copies of the E2F1 promoter. Claim 1 in application 09/714,409 states that there are E2F binding sites in the adenoviral vector, and claim 1 in application 10/303,598 the adenoviral vector comprises one E2F transcriptional nucleotide regulatory site. Since neither claim 1 in either application 10/303, 598 or 09/714,409 state that their respective adenoviral vectors comprise the same genome as Onxy-411, it still remains that claim 1 of the instant application remains obvious over claim 1 in applications 10/303, 598 and 09/714,409. Thus for reasons of record and above the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 in line recites the limitation “the properties of Onyx 411” with regard to the adenoviral vector that is made by the claimed method. It is unclear what the metes and bounds are of the properties of Onyx 411.

Claim 40 teaches a method of making an adenoviral vector comprising infecting cells with a second adenoviral vector comprising 2 E2F responsive transcriptional nucleotide regulatory sites, which then results in the production of the adenoviral vector of claim 1. Claim 1

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is an adenoviral vector comprising one E2F responsive transcriptional regulatory site. It is unclear how the claimed method of claim 40 results in the adenoviral vector of claim 1 with only one E2F site. Where is the second E2F site that was used in the vector of claim 40?

Claim 41 recites the limitation “consisting of R1, R2, or R3” in 2 of the claim. The term “or” should be “and”.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

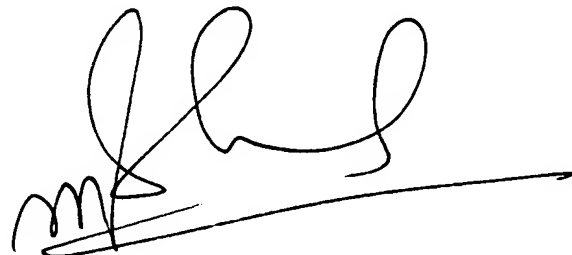
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, PhD

A handwritten signature in black ink, appearing to read 'R. Shukla', with a long horizontal line extending to the right.

**RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER**